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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/535,220	05/17/2005	Juan Carlos Domingo Pedrol	256731	9405

21831 7590 07/24/2009

Cozen O'Connor
250 PARK AVENUE
NEW YORK, NY 10177

EXAMINER	
ZAREK, PAUL E	

ART UNIT	PAPER NUMBER
1617	

NOTIFICATION DATE	DELIVERY MODE
07/24/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

pto@cozen.com
ggress@cozen.com

Office Action Summary	Application No.	Applicant(s)	
	10/535,220	DOMINGO PEDROL ET AL.	
	Examiner	Art Unit	
	Paul Zarek	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE _3_ MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 May 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *16-22 and 25-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *16-22 25-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 05/26/2009 has been entered.

Status of the Claims

2. Claim 16 has been amended and Claims 15, 23, and 24 have been cancelled by the Applicant in correspondence filed on 05/26/2009. Claims 16-22 and 25-28 are currently pending. This is the third Office Action on the merits of the claim(s).

RESPONSE TO ARGUMENTS

3. Examiner acknowledges submission of Application Data Sheet for the perfection of the claim for the benefit of prior-filed international application PCT/IB03/05673. The effective filing date of the instant application is 12/01/2003. In perfecting the claim to the international application, Applicants have also perfected the right of foreign priority. The date of foreign priority is 12/05/2002.

4. Claims 23 and 24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant

regards as the invention. This rejection is moot in light of Applicants' cancellation of the Claims 23 and 24.

5. Claims 15-22, and 25-28 were rejected under 35 U.S.C. 102(e) as being anticipated by Pacioretty and Babish (US PreGrant Publication No. 2004/0106591). This rejection is moot in light of Applicants cancellation of Claim 15 and amendment to Claim 16, from which all other claims depend.

6. Claims 1, 23, and 24 were rejected under 35 U.S.C. 103(a) as being unpatentable over Pacioretty and Babish (above). Examiner notes that "Claim 1" in the statement of rejection was intended to read "Claim 15." This rejection is moot in light of Applicants' cancellation of Claims 15, 23 and 24.

7. Claims 15-28 were rejected under 35 U.S.C. 103(a) as being unpatentable over Holstein, et al. (Experimental and Clinical Endocrinology and Diabetes, 2001) in view of and Connor, et al. (Annals of the New York Academy of Sciences, 1993). This rejection is moot in light of Applicants' amendment to Claim 16 and cancellation of Claims 15, 23, and 24.

8. Claims 16-22 and 25-28 are examined on their merits, herein.

Claim Rejections - 35 USC § 112 (1st paragraph)

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 16-22 and 25-28 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Amended Claim 16, from which claims 17-22 and 25-28 depend, is drawn to a method of treating lipodystrophy consisting of administration of at least 100 mg/day of docosahexaenoic acid (DHA) to a patient concomitantly receiving highly active anti-retroviral therapy (HAART). Examiner interprets the phrase "consisting of" to mean that said patient receives only DHA, with no additional components (excipients, carriers, etc). There is nothing in the original disclosure indicating administration of only DHA for treatment of lipodystrophy. As such, the phrase "consisting of" represents new matter. Moreover, the instant specification does not provide written support for a method of treating lipodystrophy consisting of administration of DHA.

11. Claim16-22 and 25-28 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

12. *In re Wands*, 858 F.2d at 736-40, 8 USPQ2d at 1403-07, set forth eight factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue." (MPEP § 2164.01(a)). The relevant Wands factors are discussed below:

a. *The breadth of the claim*: The rejected claims are drawn to a method of treating lipodystrophy consisting of administration of DHA to patients concomitantly receiving HAART. "Consisting of" is closed language not permitting the presence of an additional ingredient, including excipients, carrier, etc.;

b. *The state of the prior art*: Pacioretty and Babish (US PreGrant Publication No. 2004/0106591, already of record) teach a method of treating fat maldistrubtion (e.g. lipodystrophy) in an HIV-infected human patient receiving anti-retroviral therapy (ART) comprising a conjugated fatty acid, such as docosahexaenoic acid (DHA) (paragraph 0059, Claims 21 and 22). Pacioretty and Babish require "pharmaceutically acceptable carrier[s]" (para 0018). Examiner found no art of DHA being administered in the absence of an additional component;

c. *Amount of direction provided by the inventor*: Applicants provide no disclosure regarding administration of DHA alone. Applicants suggest that the pharmaceutically acceptable diluents, excipients and/or carriers would depend upon the route of administration (pg 5, lines 3-6);

d. *Existence of working examples*: Examples 1 and 2 disclose administration of tuna oil, which comprises 70% DHA. There are no examples where DHA alone is administered; and,

e. *Quantity or experimentation needed to make or use the invention based on the content of the disclosure*: The composition in which a drug or molecule resides influences its pharmacokinetics. Administration of DHA alone constitutes administration of a pure oil. It is unclear how pure DHA oil would behave, *in vivo*, following oral or

parenteral administration. The art does not compensate for the lack of guidance in the instant specification regarding the administration of only DHA and its efficacy for treating lipodystrophy. As such, undue and unpredictable experimentation would be required to use the invention as claimed. Therefore, the instant specification is not considered sufficiently enable one of ordinary skill in the art to use the invention at the time of filing.

Conclusion

13. Claims 16-22 and 25-28 are rejected.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul Zarek whose telephone number is (571) 270-5754. The examiner can normally be reached on Monday-Thursday, 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

PEZ

/San-ming Hui/
Primary Examiner, Art Unit 1617